UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

RASMUSSEN INSTRUMENTS, LLC, Plaintiff, v. DEPUY SYNTHES PRODUCTS, INC., DEPUY SYNTHES SALES, INC., AND MEDICAL DEVICE BUSINESS SERVICES, INC., Defendants.	)	C.A. No. 1:20-cv-11807-TSH

DEFENDANTS' MEMORANDUM IN SUPPORT
OF THEIR RULE 59 MOTION FOR A NEW TRIAL

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I. INTRODUCTION

Pursuant to Rule 59, Defendants move for a new trial for the following reasons:

- The verdict form should have included a question on whether plaintiff proved itself to be the owner of the asserted patents, and the failure to include such a question resulted in a miscarriage of justice.
- The jury was instructed to apply legally incorrect claim constructions for "femoral component," "tensioning apparatus," and "threaded member", unfairly prejudicing DePuy.
- Dr. Isaacson's unreliable survey and opinions unfairly prejudiced the jury's determinations of infringement and damages, and the resulting jury verdict was a miscarriage of justice.
- The jury's $20 million damages award was infected by the erroneous admission of unreliable opinion testimony from Dr. Isaacson and Dr. Putnam that skewed the range of possible damages, the admission of Dr. Putnam's opinions that did not account for plaintiff's failure to mark under § 287(a), and the failure to charge the jury regarding the unavailability of future damages in response to a question during deliberations, and necessitates, at a minimum, a new trial on damages.

II. LEGAL STANDARD

The Court may order a new trial "on all or some issues . . . after a jury trial for any reason for which a new trial has heretofore been granted in an action at law in federal court." Fed. R. Civ. P. 59(a)(1)(A). "The rule creates the opportunity to correct a broad panoply of errors, in order to prevent injustice." *Perez-Perez v. Popular Leasing Rental, Inc.*, 993 F.2d 281, 283 (1st Cir. 1993). A new trial is warranted where "the verdict is against the weight of the evidence." *Jennings v. Jones*, 587 F.3d 430, 436 (1st Cir. 2009). This Court has not just "the power" but the "duty to order a new trial whenever, in its judgment, the action is required to prevent injustice." *Id.* (quoting *Kearns v. Keystone Shipping Co.*, 863 F.2d 177, 181 (1st Cir. 1988)).

III. ARGUMENT

A. The Court Should Grant A New Trial In View Of The Failure To Include DePuy's Requested Question On Patent Ownership On The Verdict Form.

The verdict form did not include a question regarding whether plaintiff had proved that it owns the '180 and '583 patents. Declining to do so prejudiced DePuy because it improperly

suggested to the jury that there was nothing for it to decide regarding a critical threshold issue on which plaintiff bore the burden of proof and that had been the subject of trial evidence and closing argument. If the Court does not grant JMOL on this issue, which it should for the reasons in DePuy's Rule 50(b) motion, then the Court should order a new trial.

To bring its action for infringement, plaintiff had to prove it owned the '180 and '583 patents. *Sicom Systems, Ltd. v. Agilent Techs., Inc.*, 427 F.3d 971, 976 (Fed. Cir. 2005); Dkt. 161 at 16 (plaintiff, in joint pretrial memo, stating that it will prove ownership of the '180 and '583 patents); Trial Tr. 13-46:14-22 (counsel for plaintiff, with respect to patent ownership: "I get it. It's our burden."). DePuy has explained in detail how plaintiff failed to meet its burden. *See* Dkt. 263, Dkt. 287, and DePuy's contemporaneous Rule 50(b) motion. Although this issue should be resolved on JMOL in DePuy's favor, to the extent it presented a jury issue, it was prejudicial for the jury not to have been given a verdict question on this threshold issue.

DePuy sought to put the ownership question to the jury (*see* Exhibit A (DePuy's proposed verdict form); Trial Tr. 11-19:3 to 11-21:17), but the Court decided not to include that question. Trial Tr. 13-5:13-15. This confused the jury, to the prejudice of DePuy, because the Court instructed the jury on the ownership issue, explaining that it was plaintiff's burden to prove by a preponderance of the evidence that it owned the patents (Trial Tr. 12-131:5-25), but gave the jury no mechanism for resolving that question.

The Court should obviate this prejudicial error by granting DePuy's Rule 50(b) motion. This would be consistent with plaintiff's view that this is a question for the Court (Trial Tr. 11-13:10-12), and with DePuy's showing that no disputed issue of material fact prevents the Court from entering the judgment DePuy seeks. Absent that outcome, this is exactly the type of prejudice that Rule 59 is designed to correct. *See Falcon Stainless, Inc. v. Rino Companies, Inc.*, No.

SACV08-00926 AHS (MLGx), 2011 WL 13130703, at *16 (C.D. Cal. Oct. 21, 2011), *aff'd*, 572 F. App'x 483 (9th Cir. 2014) (granting motion for new trial where the court omitted defendant's requested affirmative defense on the verdict form); *William Hablinski Architecture v. Amir Const. Inc.*, 332 F. App'x 363, 364 (9th Cir. 2009) (affirming trial court's grant of a new trial where verdict form did not include question on apportionment of profits). To conclude otherwise would be against the interest of justice.

If the Court does not grant DePuy's renewed motion for JMOL, it should order a new trial.

B. The Court Should Grant A New Trial Because The Jury Was Charged With Incorrect And Confusing Constructions Of "Femoral Component," "Tensioning Apparatus," And "Threaded Member."

The jury's finding that DePuy's accused Balanced Sizer instrument infringed claims 6, 9, 13, and 18 of the '180 patent (Dkt. 281 at 2–6) was based on Judge Young's erroneous constructions of the terms "femoral component" (claims 6, 9, and 13), "femoral component comprising an intramedullary rod . . . with an opening" (claim 18), "tensioning apparatus" (claims 6 and 18), and "threaded member" (claims 9 and 13). The claim-construction charges given to the jury were erroneous and confusing, and highly prejudicial to DePuy. A new trial is warranted.

1. Judge Young's Claim-Construction Rulings.

During claim-construction proceedings, the parties disputed the meanings of "femoral component," "tensioning apparatus," and "threaded member." DePuy proposed that the claim elements reciting a "femoral component" in claims 6, 9, and 13 should be construed pursuant to 35 U.S.C. § 112, ¶ 6 as "means-plus-function" limitations limited to the corresponding structures disclosed in the specification: "(1) femoral intramedullary rod 13 (Fig. 32); and (2) femoral intramedullary rod 113 [(Fig. 43)]." Dkt. 40-1 at A-5. DePuy proposed that "femoral component" in claim 18 should be construed as "a hollow femoral intramedullary rod." *Id.* at A-8. DePuy proposed that the "tensioning apparatus" elements of claims 6 and 18 also be construed as means-

plus-function limitations limited to the corresponding structures that, in flexion, include a hollow barrel-shaped structure (*i.e.*, "femoral mount 15" and "threaded barrel 115") that is part of a femoral IM rod. (*Id.* at A-10–A-12.) DePuy proposed that "threaded member" of claims 9 and 13 be construed as "a bolt with a head and an externally threaded shaft." (*Id.* at A-15.) Rasmussen proposed that each disputed term be given its "plain and ordinary" meaning (*id.* at A-5, A-8, A-10–A-12, A-15), but never said what those meanings were. *See* Dkt. 100 at 31, 36, 41.

At the *Markman* hearing, Judge Young tentatively rejected DePuy's means-plus-function constructions while acknowledging the inherent danger in adopting Rasmussen's proposed "plain and ordinary meaning" constructions without a clear understanding of what Rasmussen contends that meaning is. Dkt. 82-1 at 23:21–24:5. He ordered further briefing consistent with his tentative ruling. *Id.* at 24:6–25:4. In subsequent briefing, the parties proposed alternative constructions of "femoral component"—DePuy proposed "femoral intramedullary rod," and Rasmussen proposed "member, component, or structural unit for positioning at a femur." Dkt. 82 at 1. Regarding "tensioning apparatus," DePuy stood on its proposed means-plus-function construction, while Rasmussen continued to maintain that it had some still-undisclosed plain and ordinary meaning. *Id.* at 2; *see also* Dkt. 100 at 40.

After briefing, Judge Young construed "femoral component" (claims 6, 9, and 13) as any "component configured to extend into a femur when seated in the femur or at the distal portion of the femur," and declined to further construe "femoral component comprising an intramedullary rod . . . with an opening" (claim 18) other than ruling that it "need not be hollow." Dkt. 100 at 47–48. He rejected DePuy's means-plus-function construction for "tensioning apparatus," noted that Rasmussen "fails to state what the plain and ordinary meaning is," yet—paradoxically—declined to construe the disputed term on the grounds that "[r]ead in context and alongside this Court's

other constructions, 'the plain and ordinary meaning of the disputed claim language is clear.'" *Id.* at 40 (quoting *Summit 6, LLC v. Samsung Elecs. Co.*, 802 F.3d 1283, 1291 (Fed. Cir. 2015)). Even Judge Young did not say what that "clear" meaning is, however. He also rejected DePuy's construction of "threaded member," construing it as "member with internal or external threads." *Id.* at 42. The Court instructed the jury to apply Judge Young's constructions, with the exception of "threaded member," for which no instruction was given. Trial Tr. 12-133:22–12-134:9.

2. These Erroneous Claim-Construction Instructions Warrant A New Trial.

"An erroneous instruction regarding claim interpretation that affects the jury's decision on infringement is grounds for a new trial." *Ecolab, Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1373 (Fed. Cir. 2002). "A party seeking to alter a judgment based on erroneous jury instructions must establish that 'those instructions were legally erroneous,' and that 'the errors had prejudicial effect.'" *Id.* (quoting *Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1281 (Fed. Cir. 2000)). Whether a jury instruction is erroneous is a question of law. *Id.*

Further, Rule 54(b) permits the Court to "revise" an interlocutory ruling, such as claim construction, "at any time before the entry of judgment adjudicating all the claims and all the parties' rights and liabilities." Fed. R. Civ. P. 54(b). Thus, "[a] district judge who inherits a proceeding from a member of the same court, for example, 'may alter previous rulings if he is convinced they are incorrect.'" *LoggerHead Tools, LLC v. Sears Holding Corp.*, No. 12 C 9033, 2017 WL 6569629, at *9 (N.D. Ill. Dec. 22, 2017) (ordering new trial and reconstruing disputed term because "the prior claim construction (and thus the jury instruction) was erroneous") (quoting *Best v. Shell Oil Co.*, 107 F.3d 544, 546 (7th Cir. 1997)). In resolving both this motion and the Rule 50(b) motion, the Court is obligated to apply the correct law: "Notwithstanding the jury's verdict, on review of a motion for JMOL the court retains the power and duty to say what the

correct law is, and then to examine the factual issues submitted to the jury and determine whether findings thereon are supported by substantial evidence and support the verdict under the law." *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 975 (Fed. Cir. 1995) (*en banc*).

3. Judge Young's Construction Of "Femoral Component" Was Erroneous.

Each asserted claim of the '180 patent requires a "femoral component" that defines an opening extending into a femur, such that the opening can receive an "elongated member" (*i.e.*, femoral IM rod) that likewise extends into the femur. The specification discloses only two such structures—both are hollow femoral IM rods. Judge Young, however, construed the term far more broadly (and favorably for plaintiff). Dkt. 100 at 47–48. That construction is inconsistent with the specification, the plain and ordinary meaning of the terms, and controlling case law, and therefore legally wrong.

(a) The Claims Recite A "Femoral Component" That Is Part Of A Tensioning Instrument.

Non-asserted independent claim 1 of the '180 patent, from which asserted claim 6 depends, and asserted independent claim 9 of the '180 patent, from which asserted claim 13 depends, recite "femoral component" elements that are substantially identical:

Claim 1	Claim 9
"A device for maintaining a ligamentous tension of a knee joint, the device comprising [] **a femoral component defining an opening**, wherein a portion of the femoral component and a portion of the opening are both **configured to extend into a femur** when the femoral component is seated in the femur . . . ."	"A device for adjusting tension in a knee joint, the device comprising [] **a femoral component defining an opening**, wherein a portion of the femoral component and a portion of the opening are both **configured to extend into a femur** when the femoral component is seated at a distal portion of the femur . . . ."

TX-1 at 22:57–62, 23:38–44 (emphases added). Asserted claims 6, 9, and 13 each therefore require "a femoral component defining an opening . . . configured to extend into a femur." *Id.*

Claim 9 further includes an "elongated member" element that "extend[s] into the opening in the femoral component." *Id.* at 23:47–48.

Non-asserted independent claim 15 of the '180 patent, from which asserted claim 18 depends, recites:

> A device for adjusting tension in a knee joint, the device comprising: **a femoral component comprising an intramedullary rod** configured to be inserted into a femur; a tibial component . . . ; and a tensioning apparatus . . . , wherein a portion of the tensioning apparatus is configured to couple **with an opening** in at least one of the femoral component and the tibial component, and **wherein the opening is configured to extend into** at least one of **the femur** and the tibia when the femoral component and the tibial component are fixed in the knee joint.

Id. at 24:10–27 (emphases added). Asserted claim 18, therefore, optionally requires "a femoral component . . . with an opening . . . configured to extend into . . . the femur" ***if*** the "tibial component" lacks an opening extending into the tibia. *Id.* Asserted dependent claim 18, however, adds the limitations to claim 15's femoral component that it "further comprises a cannulated insert that defines the opening, receives the intramedullary rod, and which is configured to be inserted into the femur . . . ." *Id.* at 24:46–49. Thus, the "femoral component" of asserted claim 18 is the femoral component with an opening optionally recited in claim 15, and, just like asserted claims 6, 9, and 13, the opening is configured to receive an IM rod/elongated member.

(b) The Specification Describes "Femoral Components" Only As Parts Of Implants, Not Instruments.

The '180 patent states that "[t]he present invention is related to the use of instruments for guiding preparation of a knee for installation of an implant during arthroplasty" (TX-1 at 1:30–32), and claims "[a] device for maintaining a ligamentous tension of a knee joint" and "[a] device for adjusting tension in a knee joint" to accomplish that purpose. *Id.* at 22:57-58; 23:38-39. The specification contains several references to "femoral components," but those refer to the part of the implant (or trial implant) that mimics or replaces the anatomy of the distal end of the femur,

not a part of an instrument. *Id.* at 1:62–66, 16:55–17:3, 21:21–23, Fig. 42, 49–51. Referring to Figure 50 (shown below), the specification states that "[f]ollowing the completed resection of the patient's knee joint, the resectioned portions of the femur 11 and the tibia 12 are replaced by a knee prosthesis or implant 200 . . . [that] generally comprises a femoral component 202 [in yellow] and a tibial component 204." *Id.* at 21:18–23.

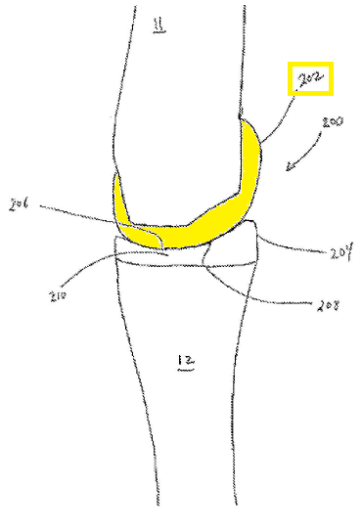


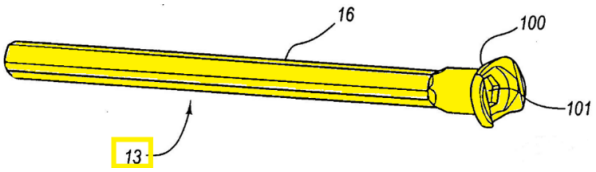
FIGURE 50

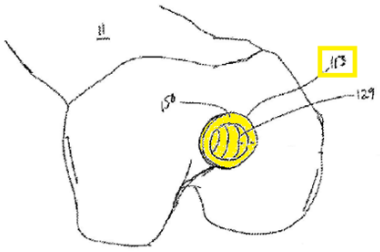
Id. at Fig. 50. The specification's use of the term "femoral component" is consistent with its plain and ordinary meaning in the field of knee arthroplasty—the part of a knee implant that mimics and replaces the distal (lower) end of the femur. *See* Dkt. 43 at 1, 14; Dkt. 56 at 2–3.[1] The claimed tensioning instruments, however, are used to guide the resection of the knee, which is completed ***before*** an implant (and its femoral component) are installed. *See* TX-1 at 22:23–36.

The specification never refers to any part of a tensioning instrument as a "femoral component." It does, however, disclose two (and only two) structures that are part of a tensioning

[1] *See also* Grace McClure and Dr. Trevor North, *Different Types of Knee Replacement Implants*, PeerWell (Oct. 3, 2016), https://peerwell.co/blog/different-types-of-knee-replacement-implants/ (defining "femoral component" as "[t]he largest, curved part that attaches to the end of the resurfaced thighbone (femur).").

device and that extend into a femur and define an opening also extending into the femur into which an IM rod or elongated member may be inserted—femoral intramedullary rod 13 (Fig. 32) and femoral intramedullary rod 113 (Fig. 43), shown below. Both are hollow IM rods. Neither is part of a knee implant. Neither is referred to as a "femoral component."





Id. at Fig. 32 (left) and Fig. 42 (right). The specification describes femoral IM rod 13 as having an "opening 101" that receives "femoral mount rod 102." *Id.* at 15:39–49, Figs. 32–33. The specification describes femoral IM rod 113 as including "threaded opening 129 [that] provides a mounting channel into which a non-threaded post 114 . . . is inserted." *Id.* at 17:16–24, Figs. 43–44. Plaintiff has conceded that these are the only two structures in the specification that extend into a femur and define an opening extending into the femur into which a femoral IM rod/elongated member is inserted. *See* Dkt. 40-1 at A-5–6. The specification neither describes nor suggests any other structure that would meet the claims' "femoral component" limitations.

(c) The Jury Instruction Was Erroneous.

Judge Young's construction of "femoral component," on which the jury here was charged, was legally erroneous; that is sufficient reason to grant a new trial.

Perhaps "femoral component" has a plain and ordinary meaning in the art. But that meaning—the part of an ***artificial knee implant*** that replaces the lower end of the femur—is inapplicable in the context of the claims, which cover ***an instrument***, not an implant. Dkt. 43 at 1, 8–9, 13–15; Dkt. 56 at 2–4. Indeed, the parties agreed that the term "femoral components," as understood in the art and identified in the specification (*e.g.*, femoral component 202 of knee

implant 200), are not the "femoral components" of the claims. *See* Dkt. 40-1 at A-5–A-6 (plaintiff not identifying "femoral component 202" as a structure corresponding to the claimed "femoral component" limitations).

Thus, "femoral component" has no plain and ordinary meaning applicable here; in the context of these claims to instruments (not implants), it is just a generic term. *See Cypress Lake Software, Inc. v. ZTE (USA) Inc.*, No. 6:17-CV-00300-RWS, 2018 WL 4035968, at *14 (E.D. Tex. Aug. 23, 2018) ("component" does "not connote structure . . . [i]nstead, the 'component' terms are coined for the purposes of the asserted patent"). The adjective "femoral" says nothing about the structure of the component, and the surrounding claim language merely explains what the femoral component does (*e.g.*, defines an opening, extends into a femur, couples with a tensioning device) rather than what structure it has. (*See* Dkt. 43 at 6–8; Dkt. 56 at 4–5.) Functional limitations like these are indefinite unless they are construed as "means-plus-function" limitations—that is, claim elements limited to the specific structures disclosed in the specification. *See Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1348 (Fed. Cir. 2015) ("[Section] 112, para. 6 will apply if the challenger demonstrates that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'") (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)).

Yet Judge Young held that the "femoral component" claim elements were not means-plus-function limitations. His reasoning was that the specification repeatedly "describes the femoral component in structural terms." Dkt. 100 at 23. But those were the "femoral components" ***of a knee implant***, not an instrument. *Id.* at 21–23. Judge Young also declared that "[t]he language of other claims likewise describes the femoral component in structural terms," but he never identified anything in the claims that showed such "structural" language. *Id.* at 23–24 (citing "generally" to

the '180 patent and also the '583 patent, which does not even use "femoral component" as a claim term). Curiously, Judge Young relied on the extrinsic evidence ***that DePuy provided***—which showed that "femoral component" had an ordinary meaning in the ***implant*** context, but not the ***instrument*** context—to show that the instrument claims provided sufficient structure. *Id.* at 24. Thus, in rejecting DePuy's means-plus-function construction, the Court erred. The common meaning of "femoral component" (as part of an ***implant***) does not apply to these claims (directed to an ***instrument***). *See, e.g.*, Dkt. 56 at 4–5.

This construction was also erroneous because it ignored how the specification describes the claimed tensioning device. The specification "is the single best guide to the meaning of a disputed term." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). As noted, the only way "femoral component" is used in the specification is to describe an implant (or trial implant) that mimics the anatomy of the lower end of a femur. TX-1 at 16:55–17:3, 21:21–23, Fig. 51; *see also* Dkt. 82 at 12. "Femoral component" is never used to refer to the claimed instrument. Instead, the specification describes only two instrument structures that extend into the femur—femoral IM rod 13 (Fig. 32) and femoral IM rod 113 (Fig. 43). Both are hollow femoral IM rods.

Judge Young invoked "claim differentiation"—an "inference" that different terms connote different claim scope, *see Innova/Pure Water v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1119-20 (Fed. Cir. 2004)—to justify adopting a construction far broader than the specification can support. *See* Dkt. 100 at 26 ("Some dependent claims indicate that the femoral component comprises a femoral intramedullary rod . . . , [but] [t]he independent claims from which these claims stem . . . do not contain such a limitation.") (citations omitted). But the claim-differentiation inference cannot expand the claims beyond the limits of what was actually invented.

E.g., *Toro Co. v. White Consol. Indus., Inc.*, 199 F.3d 1295, 1302 (Fed. Cir. 1999). In *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296 (Fed. Cir. 2011), the Federal Circuit held that a district court erred by construing the term "body" to encompass syringe bodies composed of multiple pieces. Although some claims recited "body" and others recited a "one piece body," the court held that it was erroneous to use the claim-differentiation inference to construe the term broadly— "the specifications do not disclose a body that consists of multiple pieces or indicate that the body is anything other than a one-piece body." *Id.* at 1304–1305. So too here. As in *Retractable Techs.*, the Court should correct the error, "tether the claims to what the specifications indicate the inventor actually invented"—which here is an instrument with a femoral component that is an IM rod—and grant a new trial governed by the correct construction. *Id.* at 1305. This is necessary so that the claim language does not become "divorced from what the specification conveys is the invention." *Id.* (citing *Phillips*, 415 F.3d at 1323–24).

4. Judge Young's Construction Of "Tensioning Apparatus" Was Erroneous.

Claims 1 and 15 of the '180 patent (from which asserted claims 6 and 18, respectively, depend) recite a device for maintaining or adjusting the tension of a knee joint that includes a "tensioning apparatus" that couples to or interposes between a "femoral component" and a "tibial component," and that varies a distance between them or moves them relative to each other. TX-1 at 22:57–23:3, 24:10–23. The term "tensioning apparatus" is never used or defined in the specification, and it has no commonly understood plain and ordinary meaning in the field of knee arthroplasty. Indeed, although plaintiff asserted that it had a plain and ordinary meaning, it refused to (or couldn't) say what that meaning was. Dkt. 100 at 36. And the claims describe the "tensioning apparatus" in only functional terms (*i.e.*, by what it does—tensioning and coupling—not by what it is). Thus, as DePuy proposed, the "tensioning apparatus" elements should have

been construed as means-plus-function limitations limited to the structures disclosed in the specification and corresponding to the tensioning and coupling functions. Dkt. 43 at 18–23; Dkt. 56 at 16–21. Every structure disclosed in the specification of a device that tensions the knee in flexion includes a barrel-like structure at the end of a femoral IM rod that couples to either an externally threaded bolt or a ratcheting device. Dkt. 43 at 5–6, 20–21.

Judge Young's refusal to construe the term (Dkt. 100 at 40) was legally erroneous because it failed to resolve a genuine dispute regarding claim scope, thereby improperly leaving claim construction to the jury. "When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Intern. Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1362 (Fed. Cir. 2018). DePuy maintained that "tensioning apparatus" had no ordinary meaning in the art, and that the elements requiring a "tensioning apparatus" should have been construed as means-plus-function limitations and accordingly limited to the disclosed structures. Dkt. 82 at 19. Rasmussen disagreed, asserting that "tensioning apparatus" had a plain and ordinary meaning, but never stating what that meaning is (a task that should not have been difficult had there been a "plain meaning"). Dkt. 100 at 40. Yet Judge Young declined to construe "tensioning apparatus" beyond saying that it was not a means-plus-function limitation. *Id.* The Court's failure to resolve this dispute is grounds for a new trial. *Ecolab*, 285 F.3d at 1373.

Judge Young should have required plaintiff to say what the "plain and ordinary meaning" of "tensioning apparatus" is, because "a patentee cannot avoid defining its own claim terms by asserting that its claims have a plain meaning." *Liebel-Flarsheim Co. v. Medrad Inc.*, No. 1:04-CV-607, 2006 WL 335846, at *6 (S.D. Ohio Feb. 14, 2006). *See also Moore U.S.A., Inc. v. Standard Reg. Co.*, No. 98-CV-485C(F), 2000 WL 876884, at *3 (W.D.N.Y. May 26, 2000) (rejecting plaintiff's assertion that the claims "are straightforward and clear and no interpretation

is required" because, by doing so, plaintiff "has improperly made itself the arbiter of whether its claims are 'clear and unambiguous'"); *Centillion Data Sys., Inc. v. Am. Mgmt. Sys., Inc.*, 138 F. Supp. 2d 1117, 1121–22 (S.D. Ind. 2001) (ordering plaintiff to provide its interpretation of disputed terms because "Centillion's explication of even the ordinary and accustomed meanings of asserted terms in a claim assists the Court" and because plaintiff "ignores what is often the crux of parties' *Markman* disputes: disputes over what the ordinary or accustomed meanings of claim terms are"). In accepting plaintiff's claim that "tensioning apparatus" has a "plain and ordinary meaning," but not demanding that plaintiff articulate that meaning, the Court failed to resolve a fundamental dispute of claim scope. Instructing the jury to apply the ordinary meaning of "tensioning apparatus" (*see* Trial Tr. 12-134:13–15) left the jury at sea as to the claims' scope.

The jury should have been told that the "tensioning apparatus" elements are means-plus-function limitations. Dkt. 43 at 18–22; Dkt. 56 at 16–21; Dkt. 82 at 19. Even plaintiff's technical expert, Dr. DeBerardino, confirmed this: When he was directly asked "What's an adjustable component within the context of these claims?" he gave a purely functional answer: "One that moves -- in context of these claims in the patent comparison, it's to be able to move the IM rod away and the femoral component away from the tibial component." Trial Tr. 12-59:4–8.[2]

Judge Young acknowledged that the specification of the '180 patent "make[s] no mention" of a "tensioning apparatus," yet he thought that "the relevant claim language recited sufficient structure." Dkt. 100 at 36. Each example that he found in the claims, though, merely says what the tensioning apparatus does, not what the structure is. *See id.* at 36–38. Claim 1 says that the tensioning apparatus "couples" to the femoral and tibial component, and that it is "selectively

[2] The parties agree there is no material difference between the "adjustable component" limitations of the '583 patent and the "tensioning apparatus" limitations of the '180 patent. (*See, e.g.*, Dkt. 42 at 15–21; Dkt. 43 at 22.)

actuated to vary a distance" between them. *Id.* at 36–46 (quoting TX-1 at 22:65–67, 23:1–3). Those are functions, not structure. Claim 15 likewise says that the tensioning apparatus is "interposed between" the femoral and tibial components. Dkt. 100 at 37 (quoting TX-1 at 24:10–27). That says *where* it is, not what structure it has. Claim 15 also says that the tensioning apparatus is "actuated to move the femoral component and the tibial component with respect to each other," and that some portion of it "couple[s] with an opening" in the femoral component or tibial component. (*Id.* at 24:18–22.) Again, those are functions, not structure.

The claims' lack of definable structure was only underscored by Judge Young's decision to construe "couples" to include "indirect" connections. The resulting construction—undefined structures, connected "indirectly"—gave the jury no definition to this critical claim limitation. Where, as here, claims describe an element "solely in relation to its function and location in the apparatus," the means-plus-function statute, 35 U.S.C. § 112, ¶ 6 , applies. *Diebold Nixdorf, Inc. v. Int'l Trade Comm'n*, 899 F.3d 1291, 1298 (Fed. Cir. 2018). *See also LG Elecs. U.S.A., Inc. v. Whirlpool Corp.*, No. CIV.A. 09-5142 GEB-ES, 2011 WL 1560592, at *10 (D.N.J. Apr. 25, 2011) ("[T]he words surrounding the claim do not add to the information about the term—they only give the origin and destination of the ice transported, without clues about the structure that transports the ice there."). Judge Young pointed to nothing in the claims that "specifies the exact structure that performs the functions in question." *TriMed Inc. v. Stryker Corp.*, 514 F.3d 1256, 1259–60 (Fed. Cir. 2008). And, like plaintiff, he never articulated what that "exact structure" could have been. Dkt. 100 at 40.

These errors, as incorporated into the jury charge, resulted in the jury impermissibly deciding questions of claim scope.

5. The Jury Was Erroneously Told To Give "Threaded Member" Its Plain And Ordinary Meaning.

The jury was (despite the fact that Judge Young construed this term, Dkt. 100 at 41) improperly told to apply the "ordinary meaning" of "threaded member." Trial Tr. at 12-134:13–15. Claim 9 recites "a threaded member that is . . . ***configured to be turned*** to vary tension in the knee joint." TX-1 at 23:49–53 (emphasis added). The term "threaded member" is not used in the specification, but there are "threaded" objects described there that meet this limitation—bolts 30, 96, 105, and 120, but nothing else. *See id.* at 9:19–42, 12:52–65, 15:50–57, 17:35–49, Figs. 6, 34, 43. These are all bolts with a head and an *externally* threaded shaft. Had the claims been construed as DePuy urged, so that "threaded member" meant "a bolt with a head and an externally threaded shaft" (Dkt. 40-1 at A-15), plaintiff would not have been able to argue that the Balanced Sizer—which possesses only an ***internally*** threaded member that is turned to vary tension—satisfied this limitation. *See* Trial Tr. 6-53:7-22 (Dr. DeBerardino pointing to "[t]he threaded member, which we saw on the prior slide ***where the internal thread's difficult to see without a bright light***," as satisfying the "threaded member" limitation) (emphasis added). The error is manifest.

6. DePuy Was Prejudiced By The Erroneous Constructions.

The prejudice to DePuy, too, is manifest. Assessing prejudice "requires [the Court] to examine whether there was sufficient evidence at trial to support a finding of infringement under a correct instruction." *Ecolab*, 285 F.3d at 1374. There was no such evidence here. No witness testified that the Balanced Sizer has—

- the same or a substantially equivalent structure to femoral IM rod 13 or femoral IM rod 113 of the '180 patent's specification; or
- a hollow femoral IM rod or any IM rod that defines an opening extending into a femur; or
- a tensioning apparatus with the same or substantially equivalent structure as the bolts or ratcheting device coupled with femoral mount 15 or threaded barrel 115 described in the specification; or

- an externally threaded bolt configured to be turned to vary tension in the knee joint.

Accordingly, under proper constructions, no reasonable jury could have found infringement.

The Court's refusal to define "tensioning apparatus" and "threaded member," and its overly broad construction of "femoral component," prejudiced DePuy by expanding the scope of the asserted claims far beyond anything that plaintiff had a right to enforce. The "significance of the claim terms undefined . . . and that were poorly defined allowed prejudicial error to creep into the trial process such that substantial justice was not done." *Avago Techs. Gen. IP PTE Ltd. v. Elan Microelectronics Corp.*, No. C 04-05385 JW, 2009 WL 8612367, at *4 (N.D. Cal. Sept. 23, 2009) (ordering new trial where deficiencies in claim construction "deprived the jury of a fair basis for deciding the infringement issue"). The Court should grant a new trial.

C. The Court Should Grant A New Trial In View Of Dr. Isaacson's Unreliable Survey And Opinions.

Prior to trial, DePuy identified severe methodological flaws warranting exclusion of Dr. Isaacson's survey under *Daubert*. Dkt. 131; Dkt. 146. Dr. Isaacson didn't just confirm those severe methodological flaws at trial—he admitted additional ones. He confirmed that the results he reported to the jury regarding "use" of the accused Balanced Sizer were unreliable and should have been excluded as prejudicial and not probative on any fact issue for the jury. As DePuy feared, the survey unfairly prejudiced the jury's determinations of infringement and damages because, absent Dr. Isaacson's testimony, plaintiff presented no evidence of DePuy or anyone else ***actually using*** the accused Balanced Sizer—let alone DePuy's inducement or contribution to the use of that instrument, nor how often it was used during the damages period. The admission of the survey was error and made the jury's verdict a miscarriage of justice.

1. Dr. Isaacson's Survey Was Unreliable, And Its Admission Improper.

Dr. Isaacson's survey was not a typical survey seeking customer opinions or beliefs.

Rather, Dr. Isaacson paid third-party surgeons to tell him whether and how often they ***actually used*** certain Attune instruments in total knee replacement surgery ("TKA"). Significantly, he included fake instruments in the list of choices provided—***he designed a survey that had wrong answers***, ostensibly as "as a quality control measure." Trial Tr. 5-46:20-21. And more than half of the respondents—***60% total***—chose wrong answers, reporting that they used fake instruments. Yet he did not acknowledge that these "quality control measure[s]" had shown his survey to be flawed. He did not discard the survey's obviously unreliable results—that 60% of American knee surgeons were using nonexistent surgical instruments. Instead, plaintiff offered the results of that survey to prove the truth of the alleged use of the accused instruments. In particular, plaintiff presented Dr. Isaacson's survey results as evidence for two factual issues on which it bore the burden of proof: (1) the fact of direct infringement (that surgeons actually used the Balanced Sizer); and (2) the amount of that direct infringement (how often those surgeons actually used the Balanced Sizer). But Dr. Isaacson's survey, methodologically flawed and yielding absurd results, was not probative on either issue. It should have been excluded. Its admission at trial, and the prejudicial use plaintiff made of it, warrants a new trial.

First, Dr. Isaacson's survey was not viable evidence that ***any*** surgeon ***actually used*** the accused Balanced Sizer in TKA surgeries, let alone the 22.5% of respondents that Dr. Isaacson reported to the jury. Trial Tr. 5-18:10-15; 5-36:21 to 5-37:2. Dr. Isaacson agreed that "in order to measure the use of that specific instrument, you have to uniquely identify it in the survey so that surgeons knew what you were talking about." Trial Tr. 5-50:12-16. Yet he admitted his survey didn't do that. Dr. Isaacson testified that the survey identified each instrument using only words, specifically a name and functional description—but no pictures (Trial Tr. 5-50:17-25)—and included the name and description "Balanced Sizer instrument (for gap-balancing surgical

technique)." TX 798.15. Dr. Isaacson conceded that this functional description was not unique, because multiple instruments in the Attune system can be used to perform a gap-balancing technique. Trial Tr. 5-52:3-7; 5-61:16 to 5-62:8.

More importantly, he was forced to admit that the accused Balanced Sizer is not even the only "Balanced Sizer instrument" in the Attune system. Trial Tr. 5-64:5-7; 5-65:3-6; TX 1006. On cross-examination, Dr. Isaacson was confronted with the MTO Attune Balanced Sizer, an instrument that indisputably does not infringe, and agreed that it was "a Balanced Sizer instrument for a gap-balancing technique." Trial Tr. 5-65:12-22. He further conceded that surgeons using this non-infringing instrument would have truthfully answered "yes" on his survey to the use of the Balanced Sizer instrument: "To the extent that [the instrument in Trial Ex. 1006, the MTO Attune Balanced Sizer] is a Balanced Sizer instrument for gap balancing surgical technique, they should have checked 'yes.'" Trial Tr. 5-67:1-13; TX 1006. So, the 22.5% of respondents who reported using a "Balanced Sizer instrument (for gap-balancing technique)" could have included zero users of the accused Balanced Sizer. Plaintiff should not have been allowed to present this shoddy, unreliable survey as evidence of infringement by the accused Balanced Sizer alone.

Further, as set forth in DePuy's *Daubert* motion and confirmed during trial, the utter lack of probative value of Dr. Isaacson's survey results regarding actual use of the accused Balanced Sizer is no surprise. The magnitude of error in the responses Dr. Isaacson received to Question 1 of his survey demonstrates that his results cannot be relied on to prove actual use of ***any*** instrument in that list. His survey produced data establishing that far more respondents claimed to have used fake instruments than real ones. Dr. Isaacson testified that of 196 qualified respondents, 84 claimed to use a Balanced Sizer instrument (perhaps the accused instrument; perhaps the one in Trial Ex. 1006—who knows?) (Trial Tr. 5-77:14-17), but 101 surgeons claimed to use a "Patella

Lateral Jig," which was a completely made-up instrument. Trial Tr. 5-77:18-19. Another 40 said they used an "Adjusted Sizer Instrument," another fake instrument. Trial Tr. 5-55:4-5-56:9. A total of 118 respondents (60%) thus chose completely made-up instruments (in fact, some chose multiple fake instruments). Trial Tr. 5-77:14-22. Dr. Isaacson didn't exclude these respondents from his survey, nor did he throw out the results as unreliable and start over—instead, he doubled down and claimed that he was "a hundred percent confident" in his survey. Trial Tr. 5-54:15-18.

Second, Dr. Isaacson's reported usage percentage of 22.8% (Trial Tr. 5-18:10-15; 5-37:20-38:3) is not a reliable accounting of how often surgeons actually use the accused Balanced Sizer in total knee replacement surgery. It is based on responses from all surgeons who selected "Balanced Sizer instrument (for gap-balancing technique)," which renders it unreliable for the same reasons set forth above—there's no reliable way to tell whether this survey included even a single user of the accused Balanced Sizer. Trial Tr. 5-29:24 to 5-30:10. Additionally, as DePuy explained in its pretrial motion to exclude Dr. Isaacson's testimony, the methodology Dr. Isaacson used to calculate this usage percentage is also fatally flawed. Dkt. 131 at 12-14. He asked each respondent to provide a percentage of TKA surgeries performed using a "Balanced Sizer instrument (for gap-balancing technique)" (Dkt. 132-1 at 7 (Survey at Q.2)), and then simply took the average of those percentages. Dr. Isaacson did not ask respondents to quantify the numerator (total number of TKA surgeries using a selected item) or denominator (total number of TKA surgeries) that they used to get that percentage. Dkt. 131 at 13. Absent data quantifying the number of surgeries used to calculate the reported percentages, the average of those percentages is not only meaningless, but would have been misleading as to the actual use percentage. *Id*. Presenting this number to the jury was prejudicial error.

2. The Admission Of Dr. Isaacson's Unreliable Survey Was Prejudicial To The Jury's Determination Of Infringement And Damages.

The admission of Dr. Isaacson's survey prejudiced the jury's determination of direct infringement and the resulting damages to plaintiff. Dr. DeBerardino told the jury that he relied on Dr. Isaacson's survey as his evidence of direct infringement. Trial Tr. 7-58:7 to 7-59:9. Setting aside that generalized survey responses such as those presented by Dr. Isaacson are not "specific instances of direct infringement" required to meet plaintiff's burden of proof, as explained in DePuy's Rule 50(b) motion, the admission of those responses colored the jury's view—for no fact witness in this case identified a single surgeon who directly infringed the patent claims. No DePuy employee identified any specific instances of direct infringement, let alone any occurring after patent issuance. Dkt. 252-3 (Edwards); Dkt. 252-5 (Heldreth). Nor is Dr. Kamara's passing assertion that he used the Balanced Sizer once in the last nine months before switching to Zimmer implants sufficient to show that DePuy induced him to use it, or contributed to his use. Trial Tr. 4-133:6-23. Nor could that single use support an award of $20 million in damages.

The failure to exclude Dr. Isaacson's unreliable survey led to a jury verdict that is a miscarriage of justice. DePuy is entitled to a new trial.

D. The Court Should Grant A New Trial On Damages In View Of The Unreliable Expert Opinions Of Dr. Isaacson And Dr. Putnam, Plaintiff's Undisputed Failure To Mark, And The Failure To Charge The Jury That Future Damages Are Not Available.

DePuy is entitled to a new trial on damages for multiple reasons.

1. The Failure To Exclude Dr. Putnam's and Dr. Isaacson's Unreliable Opinions Warrant A New Trial On Damages.

DePuy moved to exclude the opinions of both survey expert Dr. Isaacson and damages expert Dr. Putnam as unreliable for numerous reasons. *See* Dkts. 131, 146, 133, 143 & 242. At trial—relying on Dr. Isaacson's survey—Dr. Putnam told the jury to award damages based on an

even 50/50 split of DePuy's total profit on all sales of the Attune knee system implanted using the Balanced Sizer from November 15, 2016 to the present. Trial Tr. 8-107:7 to 8-108:5. As DePuy feared (and indeed, predicted), the admission of those unreliable expert opinions prejudiced the jury's determination of damages, inappropriately skewing the verdict. Plaintiff was erroneously permitted to present astronomical damages to the jury through the testimony of Drs. Isaacson and Putnam, and this error is not cured by the fact that the jury awarded only 10% of the damages Dr. Putnam opined would be appropriate. *See*, *e.g., Virnetx, Inc. v. Cisco Sys. Inc.*, 767 F.3d 1308, 1333 (Fed. Cir. 2014) (vacating damages award and noting that "use of [the 'Nash bargaining solution' 50/50 split] methodology would nevertheless run the significant risk of inappropriately skewing the jury's verdict").

(a) Dr. Isaacson's Unreliable Survey, And Dr. Putnam's Opinions Relying On It, Prejudiced The Jury.

As explained above, the Court should order a new trial on noninfringement and damages in view of the failure to exclude Dr. Isaacson's survey. The erroneous admission of Dr. Isaacson's survey at least warrants a new trial on damages for the same reasons discussed in Section C, above. Further, the way in which Dr. Putnam used Dr. Isaacson's survey provides additional reasons to grant a new trial on damages.

For one, Dr. Isaacson's survey only asked surgeons about use during a 12-month period of time, but Dr. Putnam took the unreliable usage rate for the Balanced Sizer and applied it to the entire damages period—and, further, assumed that it would increase over time. Trial Tr. 8-25:10-12; 8-78:3 to 8-79:11.

For another, Dr. Isaacson limited his survey to surgeons working in the United States—he did not survey any surgeons outside the United States (Trial Tr. 5-49:4-22)—yet Dr. Putnam used Dr. Isaacson's usage rate for the Balanced Sizer to calculate a usage rate outside the United States

and applied that rate to foreign sales of the Attune system. Trial Tr. 8-23:25 to 8-24:16. This unwarranted extrapolation of Dr. Isaacson's flawed survey results was particularly prejudicial to DePuy, because plaintiff presented ***no evidence whatsoever of any acts of infringement (under any theory) occurring outside of the United States***—that was Dr. Putnam's sole reason for improperly adding over $86 million in foreign sales to his damages base. TX-838.1.

For these reasons, the admission of Dr. Isaacson's survey warrants a new trial on damages.

(b) The Admission Of Dr. Putnam's Unreliable Opinion Regarding A 50/50 Split Of Profits Was Error.

As explained in DePuy's pre-trial *Daubert* motion, which is incorporated herein by reference, Dr. Putnam's damages opinion should have been excluded as contrary to both binding legal precedent and the facts. Dkt. 133; Dkt. 143. His conclusion that DePuy and plaintiff would simply split the profits 50/50 (Trial Tr. 8-58:16-19) is based on an arbitrary application of the so-called "Nash bargaining solution" that has been repeatedly rejected by the Federal Circuit and other courts. *See, e.g.*, *VirnetX*, 767 F.3d at 1331-34; Dkt. 121 at 8-9 (collecting cases). And the evidence did not support Dr. Putnam's bare assertion of equal bargaining power. As he confirmed at trial, Dr. Putnam's opinion is based on two incorrect premises: (1) DePuy had no acceptable alternatives; and (2) the accused Balanced Sizer was the sole motivation for the surgeon's decision to use the Attune knee system in all surgeries in which it was used. Trial Tr. 8-47:12-13; 8-111:5-8; 8-111:25 to 8-112:2. Both were debunked at trial.

First, not only did Dr. Putnam apply the wrong standard for acceptable non-infringing alternatives (Dkt. 133 at 5-7), but trial testimony confirmed that Dr. Putnam's opinions were based on a false premise—DePuy did, in fact, have acceptable non-infringing alternatives available, including spacer blocks, lamina spreaders, the MTO Attune Balanced Sizer, and the Balancing Blocks, the last of which were ultimately held non-infringing by the jury. *See, e.g.*, Trial Tr. 3-

108:5-7; 4-122:10-11; 10-53:22-24; 10-85:1-8; 10-91:17-22. As to the Balancing Blocks, the jury's finding that they don't infringe alone warrants a new damages trial, because Dr. Putnam acknowledged that his opinion depended on the assumption that the "obviously available" Balancing Blocks are "not an alternative because they infringe Dr. Rasmussen's patents." (Trial Tr. 8-49:4-10), and Dr. DeBerardino further admitted that the Balancing Blocks were an acceptable alternative to the Balanced Sizer. Trial Tr. 7-103:5-13. But Dr. Putnam did not present any opinion to the jury accounting for the Balancing Blocks—or any other instrument for that matter—being an acceptable, non-infringing alternative.

Second, overwhelming evidence established that instruments play at best a limited role in driving implant sales. *See, e.g.*, Trial Tr. 6-46:7-10; 4-130:17-22; 9-134:5-12; 10-57:22 to 10-59:2. Not a single witness testified that the Balanced Sizer was, as Dr. Putnam contended, the sole motivation for using the Attune system. Yet Dr. Putnam maintained that the Balanced Sizer not only drove demand, but that DePuy would have lost ***every single sale*** of an Attune implant installed using the Balanced Sizer—***without exception***—if DePuy could not offer the Balanced Sizer. Trial Tr. 8-110:19-22; 8-111:25 to 8-112:2.

Just as DePuy feared, allowing Dr. Putnam to present his arbitrary 50/50 split and the resulting excessive damages amount skewed the jury's verdict. *See* Dkt. 133 at 11. The Court should grant a new trial on damages.

2. Plaintiff's Undisputed Failure To Mark Warrants A New Damages Trial.

As set forth in DePuy's renewed motion for JMOL, there is no dispute that plaintiff failed to mark pursuant to 35 U.S.C. § 287(a). The testimony of plaintiff's own witnesses proved as much (*id.*), and so plaintiff should have been limited to damages occurring after October 2, 2020, the date the Complaint was filed. DePuy moved to preclude Dr. Putnam from presenting opinions

regarding damages prior to the filing of the Complaint (Dkt. 246), but Dr. Putnam's opinions for the entire damages period were admitted. By his own calculation, if the filing of the Complaint triggered damages, Dr. Putnam's damages opinion should have been reduced by 74%. Trial Tr. 8-39:10-13. The admission of Dr. Putnam's much-higher pre-Complaint damages number skewed the range of potential damages presented to the jury, and warrants a new trial on damages.

3. The Failure To Charge The Jury Regarding The Unavailablity Of Future Damages Was Erroneous And Prejudicial.

Prior to trial, DePuy informed plaintiff and the Court that the Balanced Sizer had been pulled from the market and sought to preclude evidence of future damages. *See* Dkt. 206; Dkt. 204. During trial, both Dr. Putnam and DePuy's expert Ms. Mulhern presented damages through December 31, 2021. *See* TX-838. During deliberations, the jury asked "is the lump sum for DePuy's usage until today or should we consider future usage until the life of the patent in 2026?" Trial Tr. 14-5:14-18. DePuy stated that the answer to that question should be "no," the jury should not consider future sales beyond December 31, 2021. Trial Tr. 14-7:2-13; 14-7:23 to 14-8:1. Over DePuy's objection, and at plaintiff's insistence, the Court instead re-read the portion of the jury instruction stating that a lump sum covers past ***and future*** infringing sales. Trial Tr. 14-5:20-25. As DePuy noted, the jury was asking a specific question regarding whether future usage—*i.e.*, usage going forward after trial—should be considered, and the instruction read to them addressed the abstract issue of what a lump sum at the time of the hypothetical negotiation covers. There was no evidence presented during trial regarding future sales—indeed, there will be no such sales. The failure to instruct the jury as DePuy requested prejudiced the jury and warrants a new trial.

IV. CONCLUSION

For these reasons, if the Court does not grant DePuy's Renewed Motion for JMOL under Rule 50(b), the Court should grant DePuy a new trial under Rule 59.

Dated: May 6, 2022

DEPUY SYNTHES PRODUCTS, INC., DEPUY SYNTHES SALES, INC. AND MEDICAL DEVICE BUSINESS SERVICES, INC.

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CERTIFICATE OF SERVICE

The undersigned certifies that, on May 6, 2022, the foregoing was filed through the Court's ECF system and will be sent electronically to the registered participants.

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